PEARSON, J.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

KAREN S. STEED Plaintiff, v. BOSTON SCIENTIFIC CORPORATION, *et al*., Defendants.	))))))))))	CASE NO. 4:17CV0824 JUDGE BENITA Y. PEARSON **MEMORANDUM OF OPINION AND ORDER** [Resolving ECF Nos. 5, 18, 19, and 22]

Pending is the Motion to Remand to State Court filed by Plaintiff Karen S. Steed (ECF No. 5) which removing Defendant Boston Scientific Corporation ("BSC") opposes (ECF No. 13). The Court has been advised, having reviewed the record, the parties' briefs, telephonic argument, and the applicable law. For the reasons set forth below, Plaintiff's motion to remand is granted.

I. Background

Plaintiff underwent a surgical procedure involving a Hydro Thermal Endometrial Ablation System- Genesys HTA Procerva Kit (the "Device"). ECF No. 1-3 at PageID #: 27-28, ¶¶ 15-27. The procedure resulted in second and third degree burns to Plaintiff's perineum, perianal area, and buttocks. ECF No. 1-3 at PageID #: 29, ¶¶ 32-41. On March 10, 2017, Plaintiff brought this products liability and medical malpractice action against Defendants Boston

Scientific Corporation ("BSC"), Salem Regional Medical Center ("Salem Regional"), and Dr. Fu-Nen Lee, M.D. ("Dr. Lee") in the Columbiana County, Ohio Court of Common Pleas. *See* Complaint, ECF No.1-3 PageID #: 23-43. As to Defendant BSC, the alleged manufacturer of the Device, the eleven-count Complaint asserts product liability claims for defective manufacture or construction (First Claim) (ECF No. 1-3 at PageID #:30-31, ¶¶ 43-53), defective design or formulation (Third Claim) (ECF No. 1-3 at PageID #: 33-34, ¶¶ 65-73), and defect due to inadequate warning or instruction (Fifth Claim) (ECF No. 1-3 at PageID #: 36-37, ¶¶ 83-90) pursuant to Ohio Revised Code §§ 2307.73(A)(1) and 2307.76. Plaintiff also alleges claims of medical malpractice against Defendants Salem Regional (Ninth Claim) (ECF No. 1-3 at PageID #: 39-40, ¶¶ 109-13) and Dr. Lee (Eleventh Claim) (ECF No. 1-3 at PageID #: 41, ¶¶ 119-24).[1]

On April 17, 2017, Defendant BSC removed the case to the Northern District of Ohio on the basis of federal question jurisdiction pursuant to 28 U.S.C. §§ 1331, 1441(a), (c)(1) and 1446. ECF No. 1 at PageID #: 1.[2] Defendant BSC avers that federal jurisdiction exists because Plaintiff's allegations are controlled and preempted by the Food and Drug Administration's

[1] Plaintiff also asserts product liability and medical malpractice claims against John/Jane Doe defendants. *See* Complaint, ECF No. 1-3 PageID #: 23-43.

[2] Contrary to Plaintiff's assertion (ECF No. 5 at PageID #: 86), the consent of Defendants Salem Regional and Dr. Lee is not required for removal of this action. Pursuant to 28 U.S.C. § 1441(c), "only defendants against whom [a claim arising under the laws of the United States] has been asserted are required to join in or consent to removal" when a civil action includes a claim arising under the laws of the United States and a claim not within the original jurisdiction of the district court. *But see* 28 U.S.C. § 1446(2)(A) ("when a civil action is removed ***solely*** under section 1441(a), all defendants . . . must join in or consent to the removal of the action.") (emphasis added).

("FDA") Premarket Approval ("PMA") process for a Class III medical device. ECF No.1 at PageID #: 1-3. On April 26, 2017, Plaintiff moved the Court to remand this action back to the Columbiana County, Ohio Court of Common Pleas on grounds that: (1) Plaintiff's claims do not raise a substantial federal issue; and (2) allowing the issue to be heard in federal court would disrupt the federal-state balance. ECF No. 5 at PageID #: 90. Defendant BSC responded (ECF No. 13); Plaintiff replied (ECF No. 14). The matter is now ripe for adjudication.

II. Standard of Review

Pursuant to 28 U.S.C. § 1441(a), "any civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or defendants, to the district court of the United States for the district and division embracing the place where such action is pending." District courts have original jurisdiction over civil actions that arise under federal law, *see* 28 U.S.C. § 1331. An action "arises under" federal law if (1) "federal law creates the cause of action," or (2) "the vindication of a right under state law necessarily turned on some construction of federal law." *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 808-09 (1986) (quoting *Franchise Tax Bd. v. Constr. Laborers Vacation Tr.*, 463 U.S. 1, 9 (1983)).

"The presence or absence of federal-question jurisdiction is governed by the 'well-pleaded complaint rule,' which provides that federal jurisdiction exists only when a federal question is presented on the face of the plaintiff's properly pleaded complaint."

Caterpillar v. Williams, 482 U.S. 386, 392 (1987); *see also* *Husvar v. Rapoport*, 430 F.3d 777, 781 (6th Cir. 2005) ("Pursuant to that 'rule,' the federal judiciary recognizes that 'the plaintiff is the master of the complaint, []a federal question must appear on the face of the complaint, and[]the plaintiff may, by eschewing claims based on federal law, choose to have the cause heard in state court.'") (quoting *Caterpillar*, 482 U.S. at 399). "The existence of subject matter jurisdiction is determined by examining the complaint as it existed at the time of removal." *Harper v. AutoAlliance Int'l., Inc.*, 392 F.3d 195, 210 (6th Cir. 2004).

Even though a claim originates in state law, the Supreme Court has recognized a "'special and small category' of cases in which arising under jurisdiction lies." *Gunn v. Minton*, 133 S. Ct. 1059, 1064 (2013).

> [F]ederal jurisdiction over a state law claim will lie if a federal issue is (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress. Where all four of these requirements are met, we have held, jurisdiction is proper because there is a serious federal interest in claiming the advantages thought to be inherent in a federal forum, which can be vindicated without disrupting Congress's intended division of labor between state and federal courts.

Id. at 1065 (citing *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 313-14 (2005)) (internal quotations omitted). The removing party bears the burden of showing that federal question jurisdiction exists. *Long v. Bando Mfg. of Am., Inc.*, 201 F.3d 754, 757 (6th Cir. 2000). "All doubts as to the propriety of removal are resolved in favor of remand." *Coyne v. Am. Tobacco Co.*, 183 F.3d 488, 493 (6th Cir. 1999).

III. Discussion

Here, the parties concede that the first two factors of the *Grable/Gunn* test are met. ECF No.5 at PageID #: 90; ECF No.13 at PageID #: 191-92. The parties agree that Plaintiff's claims raise the issue of whether Defendant BSC complied with the requirements of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* *See* ECF No.1 at PageID #: 1-2, ¶¶ 2-5 ("Plaintiff pleads violations of state law [that are] truly based upon the federal regulatory system—the FDA, [therefore,] Plaintiff's right to relief turns on resolution and interpretation of the federal-law questions"); ECF No. 5 at PageID #: 93 ("[Plaintiff's state law] claims essentially run parallel to the federal regulations for device manufacturers. . . . [and] may be proven by evidence of conduct violating the [FDCA]."). Accordingly, and in the interest of judicial efficiency, the Court considers below only the parties' arguments as to whether Defendant BSC has met the third and fourth factors of the *Grable/Gunn* test—substantiality and federal-state balance. *See* *Gunn*, 133 S. Ct. at 1065; *Grable*, 545 U.S. at 314.

A. Substantiality

For an issue to be substantial, the Court must "look[] to the importance of the issue to the federal system as a whole." *Gunn*, 133 S. Ct. at 1066. It is clear from the parties' briefs that federal courts are split in their interpretation of this third factor. The Sixth Circuit has not considered the issue in the context of FDA-regulated products since the Supreme Court's ruling

in *Gunn*.[3] But, post-*Gunn*, the majority of federal courts considering the issue have remanded these actions and held that state tort claims concerning FDA-regulated products do not raise a substantial federal issue, despite the claims' reliance on violations of the FDCA. *See, e.g.,* *Schilmiller v. Medtronic, Inc.*,44 F. Supp. 3d 721, 731 (W.D. Ky. 2014) (" [I]t is not enough that the plaintiff's state law claims arise under the backdrop of a federal issue . . . .[T]he importance of the federal issue must 'transcend[] the parties.'"); *Goade v. Medtronic*, No. 13-5123, 2013 WL 6237853, at *5 (W.D. Mo. Dec. 3, 2013) ("This degree of importance has been found only when the Government's operations are affected by the federal issue."); *Carmine v. Poffenbarger*, 154 F. Supp. 3d 309, 318 (E.D. Va. 2015) ("None of the issues in this case would affect the Government's operation. The disputes related to whether medical manufacturers designed, manufactured, and promoted an unreasonably dangerous product."); *Waitz v. Yoon*, No. 1:14-cv-2875-MHC, 2015 WL 11511577 (N.D. Ga., June 30, 2015) ("The federal issue here carries no substantial significance to the federal system as a whole but rather involves purely state law claims that revolve around a federal regulatory scheme.").[4]

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[3] The Court notes that the Sixth Circuit has announced four factors that the Court must consider under the "subtantial-federal-issue doctrine" in *Mikulski v. Centerior Energy Corp.*, 501 F.3d 555, 570 (6th Cir. 2007). However, *Mikulski* did not consider the most recent discussion of the substantiality factor by the Supreme Court in *Gunn*.

[4] The Court recognizes that the Medtronic cases cited involved claims of products liability and medical malpractice involving the off-label use of an FDA-regulated biologic product—specifically, a bone graft product used during spinal fusion surgeries. The Court finds the parties' attempts to distinguish these cases based on the type of product at issue (*e.g.*, medical device, biologic, drug, etc.) unavailing. At the crux of the removing

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See also *Sangimino v. Bayer Corp.*, No. C 17-01488 WHA, 2017 WL 2500904, at *1 (N.D. Cal. June 9, 2017) (remanding action to state court because plaintiffs claims against manufacturer alleging a defective permanent contraceptive device did not raise substantial federal issue).[5]

Still, other federal courts have denied motions to remand and held that state tort claims concerning FDA-regulated products raise a substantial federal issue. However, the Court recognizes that the cases, on which Defendant BSC's argument chiefly relies, did not analyze the third *Grable/Gunn* factor under the standard for substantiality that was announced in *Gunn*. *See* *H.R. ex rel. Reuter v. Medtronic, Inc.*, 996 F. Supp. 2d 671 (S.D. Ohio 2014) (Black, J.); *Jenkins v. Medtronic*, Inc., 984 F. Supp. 2d 873 (W.D. Tenn. 2013). Moreover, the Southern District of Ohio subsequently ruled in favor of remand on the same issue and recognized that it did not consider *Gunn* when it decided *Reuter*. *See* *Baker v. UC Health*, No. 1:16-CV-00853-TSB, 2017 WL 510271, at *6 (S.D. Ohio Feb. 8, 2017) (Black, J.) ("However, that decision [in *Reuters*] did

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[4](...continued)
parties' arguments in each instance is the pursuit of federal question jurisdiction based on the FDA's regulation of the product's use, safety, or effectiveness (be it a medical device, biologic, or drug) pursuant to the FDCA. Each case disputes whether the defendants designed, manufactured, or promoted an unreasonably dangerous product. Accordingly, in deciding whether to remand this action, the Court finds no reason to distinguish post-*Gunn* case law based on the nature of Plaintiff's claims.

[5] The Court also recognizes that, in support of its arguments on the federal-state balance, Defendant relies on a conflicting ruling out of the Western District of North Carolina on a motion to remand involving the same permanent birth control device at issue in *Sangimino*. *See Burrell v. Bayer Corp.*, Case No. 1:17-cv-00032-MOC-DSC (W.D.N.C. Mar. 17, 2017). In *Burrell*, however, the Court did not consider the refined substantiality standard announced in *Gunn*. *See* Order, ECF No. 28 in Case No. 1:17cv-0032-MOC-DSC (W.D.N.C.) at PageID #: 6-8.

not take into account the United States Supreme Court's holding in *Gunn*[.] *Gunn* clarified the substantiality inquiry to require that the disputed federal issue be "significant to the federal system as a whole.'").

The Court finds Defendant BSC's argument that there is significant interest in "adjudicating the safety and effectiveness concerns . . . in a unified federal court system" unpersuasive. ECF No. 13 at PageID #: 192. The gist of Defendant BSC's argument is that Plaintiff's state tort claims raise a substantial federal issue because the Device required the approval and continuous review of the FDA. ECF No.1 at PageID #: 1-3, ¶¶ 2-5. The Court is inclined to rule in harmony with those federal courts that analyzed the substantiality of the federal issue when a plaintiff's complaint involves violations of the FDCA pursuant to the standard announced by the Supreme Court in *Gunn*—that is, by focusing on the importance of the issue to the federal system as a whole. While the federal question at issue in the present case is significant to the parties, it does not transcend the parties, affect the government's operations, or challenge federal law in a manner evidencing importance of the issue to the federal system as a whole.

Accordingly, Defendant BSC has not met its burden of showing that federal question jurisdiction exists under § 1331.

B. Federal-State Balance

Even if Plaintiff's claims raise a substantial federal issue, should the Court exercise its jurisdiction in this case, it would likely upset the federal-state balance approved by Congress.

Congress has not provided a private right of action under the FDCA. *See Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 806-07 (2014) ("[T]he FDCA does not create or imply a private right of action for individuals injured as a result of violations of the Act[.]") (quoting *Franchise Tax Bd. v. Constr. Laborers Vacation Tr.*, 463 U.S. 1 (1983)); 21 U.S.C. § 337(a). Nor has Congress preempted all state remedies under the FDCA; discussed *infra*. While the lack of a private right of action does not by itself preclude federal jurisdiction, the combination of its absence and the absence of preemption is "an important clue to Congress's conception of the scope of the jurisdiction to be exercised under 1331." *Grable*, 545 U.S. at 318 (2005).

Defendant BSC's argument that the federal-state balance will not be interrupted "in light of the extraordinary federal involvement in the very issues that are at the heart of this case, and the small number of medical devices subject to such extraordinary federal oversight" is unpersuasive. ECF No. 1 at PageID #: 2. Accordingly, Defendant fails to meet the fourth factor under the *Grable/Gunn* test.

C. Preemption

Finally, the Court finds Defendant BSC's preemption arguments unavailing. While the Medical Device Amendments ("MDA") to the FDCA contains a preemption provision, 21 U.S.C. § 360k(a), it has long been settled that a federal court may not exercise jurisdiction on the basis of a defense, including preemption, alone. *Caterpillar*, 482 U.S. at 392; *see Franchise Tax Bd.*, 463 U.S. at 14. Moreover, preemption under the MDA does not "prevent a State from providing a damages remedy for claims premised on a violation of the FDA regulations; the state duties in

such a case 'parallel,' rather than add to, federal requirements." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008).

IV. Conclusion

For the foregoing reasons, the Court grants Plaintiff Karen S. Steed's Motion to Remand to State Court (ECF No. 5). The case is remanded to the Columbiana County, Ohio Court of Common Pleas forthwith. Defendant BSC's motion to dismiss (ECF No. 11) remains pending and shall be transmitted to the Columbiana County, Ohio Court of Common Pleas.

Defendant BSC's motion for leave to file sur-reply brief *instanter* (ECF No. 18) is granted. Plaintiff's motion to strike (ECF No. 19) is denied. Defendant BSC's motion for a consolidated response date (ECF No. 22) is denied as moot.

IT IS SO ORDERED.

July 12, 2017
Date

/s/ Benita Y. Pearson
Benita Y. Pearson
United States District Judge